

§ 423.1018

statement only if the party shows good cause.

§ 423.1018 Notice and effect of initial determinations.

(a) *Notice of initial determination*—(1) *General rule.* CMS, as required under 422.756(f)(2), mails notice of an initial determination to the affected party, setting forth the basis or reasons for the determination, the effect of the determination, the party's right to a hearing, and information about where to file the request for a hearing.

(b) *Effect of initial determination.* An initial determination is binding unless—

- (1) The affected party requests a hearing; or
- (2) CMS revises its decision.

§ 423.1020 Request for hearing.

(a) *Manner and timing of request.* (1) A Part D sponsor is entitled to a hearing as specified in 423.1006 and may file a request with the Departmental Appeals Board office specified in the initial determination.

(2) The Part D sponsor or its legal representative or other authorized official must file the request, in writing, to the appropriate Departmental Appeals Board office, with a copy to CMS, within 60 calendar days from receipt of the notice of initial determination, to request a hearing before an ALJ to appeal any determination by CMS to impose a civil money penalty.

(b) *Content of request for hearing.* The request for hearing must—

- (1) Identify the specific issues, and the findings of fact and conclusions of law with which the affected party disagrees; and
- (2) Specify the basis for each contention that a CMS finding or conclusion of law is incorrect.

§ 423.1022 Parties to the hearing.

The parties to the hearing are the affected party and CMS, as appropriate.

§ 423.1024 Designation of hearing official.

(a) The Chair of the Departmental Appeals Board, or his or her delegate, designates an ALJ or a member or members of the Departmental Appeals Board to conduct the hearing.

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(b) If appropriate, the Chair or the delegate may substitute another ALJ or another member or other members of the Departmental Appeals Board to conduct the hearing.

(c) As used in this part, “ALJ” includes a member or members of the Departmental Appeals Board who are designated to conduct a hearing.

§ 423.1026 Disqualification of Administrative Law Judge.

(a) An ALJ may not conduct a hearing in a case in which he or she is prejudiced or partial to the affected party or has any interest in the matter pending for decision.

(b) A party that objects to the ALJ designated to conduct the hearing must give notice of its objections at the earliest opportunity.

(c) The ALJ will consider the objections and decide whether to withdraw or proceed with the hearing.

(1) If the ALJ withdraws, another ALJ will be designated to conduct the hearing.

(2) If the ALJ does not withdraw, the objecting party may, after the hearing, present its objections to the Departmental Appeals Board as reasons for changing, modifying, or reversing the ALJ's decision or providing a new hearing before another ALJ.

§ 423.1028 Prehearing conference.

(a) At any time before the hearing, the ALJ may call a prehearing conference for the purpose of delineating the issues in controversy, identifying the evidence and witnesses to be presented at the hearing, and obtaining stipulations accordingly.

(b) On the request of either party or on his or her own motion, the ALJ may adjourn the prehearing conference and reconvene at a later date.

§ 423.1030 Notice of prehearing conference.

(a) *Timing of notice.* The ALJ will fix a time and place for the prehearing conference and mail written notice to the parties at least 10 calendar days before the scheduled date.

(b) *Content of notice.* The notice will inform the parties of the purpose of the conference and specify what issues are